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10/815,351

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EXAMINER

BADIO, BARBARA P

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/815,351  
Filing Date: April 01, 2004  
Appellant(s): VANRHEENEN, VERLAN H.

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Gunther J. Evanina  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed January 14, 2009 appealing from the Office action mailed August 18, 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

### **(8) Evidence Relied Upon**

WO 01/47945                      KIM et al.                      7-2001

Kim et al., US 2002/0025951 A1, 2002.

Berge et al., Pharmaceutical salts. Journal of Pharmaceutical Sciences, Vol. 66, No. 1, (1977), pages 1-19.

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 2002/0025951 or WO 01/47945) in view of Berge et al.

Kim et al. teaches the instantly claimed compound, i.e., 17 $\alpha$ -acetoxy-21-methoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione and its antiprogestational properties (see **US 2002/0025951**, especially sections 0001,0005-0007, 0024, 0028-0031 and Examples IX; **WO 01/47945**, see Abstract; page 20 and Figure 2, compound #11 ).

The instant claims differ from the reference by reciting specific salts, i.e., hydrochloride or hydrobromide salt thereof. However, the conversion of pharmaceutical agents into a salt form is routine in the pharmaceutical art. As discussed by Berge et

al., the chemical, biological, physical and economic characteristics of medicinal agents can be manipulated and optimized by conversion to a salt form (see the entire article). Berge also teaches several commercially marketed salts, including the hydrochloride and hydrobromide salts that have FDA approval (see page 2, Table I). The claimed salts are prima facie obvious based on the teachings of the prior art and the level of skill of the ordinary artisan in the pharmaceutical art.

#### **(10) Response to Argument**

Applicant argues (a) the prior art does not enable the skilled artisan in the art to make the claimed salts and (b) the declaration of Verlan H. Van Rheenen shows that it was not known, nor obvious, how to make the claimed salts. Applicant's argument was considered but not persuasive for the following reasons.

17 $\alpha$ -acetoxy-21-methoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione was known in the art at the time of the present invention as evident by Kim et al. Berge was utilized for its teaching of the importance of pharmaceutical salts, i.e., the manipulation of the chemical, biological, physical and economic characteristics of medicinal agents.

The claimed invention is the hydrochloride and hydrobromide salts of the compound taught by Kim. The steroid art teaches the hydrochloride and hydrobromide salts of a vast number of steroid compounds. The art also teaches processes for making said salts as shown by US 4,451,405 (Examples 6-10) and US 3,723,524 (Example L) noted in the Office Action dated August 14, 2008. The examiner notes that

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the processes taught by the cited patents are similar to that of the instant specification, i.e., reaction of the free base of the desired compound with the appropriate acid, for example, hydrochloric or hydrobromide acid. Based on knowledge of the skilled artisan as to the importance of salts of pharmaceutical agents and the FDA approval of hydrochloride and hydrobromide salts of pharmaceuticals, it is the examiner's position that the claimed salts are prima facie obvious.

The declaration of Verlan H. Van Rheenen centers on applicant's opinion that the salts of the compound of Kim were difficult to obtain. However, the issue is not applicant's process of making the salts but whether said salts would have been obvious to the skilled artisan in the art at the time of the present invention. Again, as evident by the cited references and the knowledge in the steroid art of both hydrochloride and hydrobromide salts, the claimed salts would have been obvious to the skilled artisan in the art at the time of the present invention. Additionally, the court has held that forming salts of known compounds are prima facie obvious. In re Williams, 89 USPQ 396 (CCPA 1951).

In summary, based on the teaching of 17 $\alpha$ -acetoxy-21-methoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione by Kim and the knowledge of pharmaceutical salts in art at the time of the present invention, such as in the steroid art, the claimed hydrochloride and hydrobromide salts of 17 $\alpha$ -acetoxy-21-methoxy-11 $\beta$ -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione are prima facie obvious.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Barbara Badio/

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Supervisory Patent Examiner, Art Unit 1612